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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,848	06/25/2002	Tomas Albrektsson	0104-0389P	5296
2292	7590	05/19/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,848

Applicant(s)

ALBREKTSSON ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-42 and 44-78 is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on June 22, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,824,568 B1 (date of patent: November 30, 2004) has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Amendment

2. Applicants' amendment of claims 38 and 67 in the reply filed on February 15, 2005 is acknowledged.

3. Applicants' addition of claims 75-78 in the reply filed on February 15, 2005 is acknowledged.

4. Applicants' filing of corrected formal drawings (Figures 11-14) in the reply filed on February 15, 2005 is acknowledged.

Claim Objections

5. Claims 38, 68-71, and 76 are objected to because of the following informalities:

a. Regarding claim 38, please substitute "portion" (see line 20) with --proximal section--.

Appropriate correction is required.

b. Regarding claim 68, please add --of said collar section-- after "surface" (see line 2).

Appropriate correction is required.

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c. Regarding claim 69, please add --of said collar section-- after “surface” (see line 2).

Appropriate correction is required.

d. Regarding claim 70, please add --of said collar section-- after “surface” (see line 2).

Appropriate correction is required.

e. Regarding claim 71, please add --of said collar section-- after “surface” (see line 2).

Appropriate correction is required.

f. Regarding claim 76, please substitute “portion” (see line 16) with --proximal section--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 68 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation “the body of the collar section” (see line 3) lacks antecedent basis.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 38, 39, 55-61, 63, 67, 73, and 75-78 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rambert et al. (GB 2 033 755 A).

As seen in Figure 1, Rambert et al. disclose a femur fixture for a hip-joint prosthesis, comprising an intraosseous anchoring structure of a generally circular cross-section for screwing laterally into a complementary bore drilled laterally into the neck of a femur after resection of the femur head to an anchored position (see entire document), the intraosseous anchoring structure comprising a head section (cylindrical thread 4 + conical bearing 5), a collar section (plate 2) having a distal surface abutting said intraosseous anchoring structure (see Figure 1), a relatively short frusto-conical proximal section (threaded rod 7), a proximal cylindrical section (recall screw 15) having a screw thread profile, and a distal end (threaded head of 15) that projects through the lateral cortex of the femur when the intraosseous anchoring structure is in the anchored position (see Figure 1; see entire document).

Response to Arguments

Applicant's arguments filed February 15, 2005 have been fully considered but they are not persuasive.

a. Applicants argue that Rambert et al. '755 "fails to disclose 'the intraosseous anchoring structure being formed from a single, one-piece member' as recited in independent claim 38". Examiner respectfully disagrees. When assembled, Rambert et al. femoral fixture is unitary, forming one single, one-piece member.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 38-42, 44-67, and 73-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrektsson et al. (WO 93/16663; previously cited in PTO-892) in view of Fontenot (US 5,639,237 A; previously cited in PTO-892) and Hansson et al. (US 5,588,838 A; previously cited in PTO-892).

Referring to Figures 1 and 3, Albrektsson et al. disclose a femur fixture comprising a proximal end, a distal end (projecting through the lateral cortex of the femur when the anchoring structure is in the anchored position), a proximal cylindrical section 2 having screw thread profile 15, a distal cylindrical section 1 having screw thread profile 3, a collar section 16 extending generally radially outwardly from the whole anchoring structure, a tapered mounting section 13 extending from a proximal end of said collar section. The diameter of distal cylindrical section 1 being less than the diameter of proximal cylindrical section 2. A tapered connecting section connects distal cylindrical section 1 to proximal cylindrical section 2. The femoral fixture can be made in one piece or in two separate parts (see page 2, lines 34-37; page 8, lines 27-30).

Although Albrektsson et al. disclose the desirability of maximal bone contact in order to achieve a physiologically appropriate load conditions (see page 3, lines 1-8; page 8, lines 17-20; page 9, lines 6-33), they did not particularly disclose the fixture as comprising a frusto-conical

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proximal section at the proximal end. However, the subject matter of a screw/fixture comprising a frusto-conical proximal section at its proximal end is well known in the art.

Fontenot '237 discloses a bone fixture comprising a proximal cylindrical section adjacent a frusto-conical proximal section at the proximal end of the fixture (see Figure 2) in order to resist displacement of the fixture, to withstand stress loads, and to increase the load bearing capacity of the fixture (see entire document). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of providing a frusto-conical proximal section at the proximal end of a bone fixture, as taught by Fontenot '237, with the femur fixture of Albrektsson et al. WO 93/16663, in order to resist displacement of the fixture, to withstand stress loads, and to increase the load bearing capacity of the fixture.

Hansson et al. '838 disclose a bone fixture comprising a proximal cylindrical section 1 adjacent a frusto-conical proximal section 10 at the proximal end of the fixture (see Figures 1-3) in order to transmit the axial loads on the fixture in a bio-mechanically correct way in such a way that the bone tissue is stressed correctly around the frusto-conical part (see column 2, line 60 to column 3, line 2). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of providing a frusto-conical proximal section at the proximal end of a bone fixture, as taught by Hansson et al. '838, with the femur fixture of Albrektsson et al. WO 93/16663, in order to transmit the axial loads on the fixture in a bio-mechanically correct way in such a way that the bone tissue is stressed correctly around the frusto-conical part.

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12. Claims 68-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albrektsson et al. (WO 93/16663; previously cited in PTO-892), as modified by Fontenot (US 5,639,237 A; previously cited in PTO-892) and Hansson et al. (US 5,588,838 A; previously cited in PTO-892), and further in view of Sotereanos (US 6,284,002 B1; previously cited in PTO-892).

Albrektsson et al. WO 93/16663, as modified by Fontenot '237 and Hansson et al. '838, disclose the subject matter of claims 38-42, 44-67, and 73-78 except for particularly disclosing the distal surface 21 of the collar section 20 as being inclined inwardly. However, Sotereanos discloses a femur fixture comprising a collar section 20 having a distal surface 32 inclined inwardly and provided with micro-beads 22/24 in order for the collar section to contact substantially all of the resected surface of the femur and to provide additional surface for bone ingrowth (see entire document). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of providing a femur fixture with a collar section having a distal surface inclined inwardly and provided with micro-beads, as taught by Sotereanos, with the femur fixture of Albrektsson et al., in order for the collar section to contact substantially all of the resected surface of the femur and to provide additional surface for bone ingrowth.

Response to Arguments

13. Applicant's arguments with respect to claims 38 and 76 have been considered but are moot in view of the new ground(s) of rejection.

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Allowable Subject Matter

14. Claim 43 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for

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the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

May 13, 2005

A large, stylized handwritten signature in black ink, consisting of a large 'J' and a large 'B'.A handwritten signature in black ink, appearing to read 'David H. Willse'.

David H. Willse
Primary Examiner